

Patent
Attorney Docket: 491,920-029
(prev 263/103)

IN THE SPECIFICATION:

Page 5, before line 23, the following paragraphs have been inserted:

FIG. 11 is a perspective view of an implant covering cut from a single sheet of ePTFE placed around a silicone elastomer shell.

FIG. 12 shows a perspective view of detail of ePTFE sheet material with a partial thickness pattern of simple cuts and/or channels which results in numerous individual villi of ePTFE and great irregularity of the surface of the material. Additional patterns of cuts or troughs may be made along any other axis as indicated, for example, by the arrows.

FIG. 13 shows a cover consisting of a molded silicone elastomer shell element with a pattern of nested hexagonal cells over the entire surface of the implant. Detail is shown. Other suitable geometric patterns may also be utilized.

Page 15, before line 5, the following paragraphs have been added:

A covering for an implant may be constructed substantially of a single sheet of ePTFE as shown for example in FIG. 4. A single sheet of ePTFE 40 is cut so as to permit it to be wrapped around the implant 10. Projectile tongues 42 may be fastened together or may be attached to separate ePTFE sheets 44 and 46 which serve as cap and bottom pieces. Appropriate cuts 48 are made in the single ePTFE sheet 40 to permit stretching of the sheet in various directions.

The implant coverings usable in connection with this invention may be manufactured from any material which promotes limited tissue ingrowth into the material, and has a high biocompatibility and low reactivity and disorganizes scar tissue at the implant/body interface. Expanded PTFE (ePTFE) is a preferred material for this invention. ePTFE is sold under the

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tradenam Goretex and is readily available. The expanded ultrastructure of this material is associated with a high degree of ultramicroporosity which invites tissue ingrowth. The material is approximately 50% air by volume. It is extremely strong yet soft, smooth, pliable, compressible and stretchable. Goretex is readily available in sheet form of various thicknesses, as round filaments of various diameters, and as tubes of various diameters and wall thicknesses. ePTFE sheeting stretches to a limited extent along a given axis, however resists stretching along all axes simultaneously. It is extremely biocompatible having been used in more than 700,000 clinical uses with no confirmed cases of material rejection. ePTFE is incorporated into surrounding tissue and is minimally encapsulated by collagen. The material is extremely strong and thereby would reduce the need for reoperation for material fatigue. It resists flexural fatigue by acting like a chain when bending forces are applied. However, it is easily cut by a knife or by using die cutting techniques. It lends itself well to machine manufacturing methods including stitching.

As in FIGS. 10 and 13, a textured molded covering 58 may be provided made of silicone elastomer or other suitable materials which serves to limit the force of scar contracture around the implant by disorganizing the scar tissue itself and also by compartmentalizing blood clot and collagen around the implant.

The "nested hexcel" structural pattern of FIGS. 10 and 13 is a preferred embodiment. All such hexcels are attached to or part of the same base which is a covering element of the implant. The textured covering 58 may form the entirety or only a portion of the covering of the implant. The hexcel with the largest perimeter 60 in this configuration is also the tallest and delimits hexagonal pools of biologic materials and tissues at the interface between the implant and the body cavity. As

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scar tissue forms it is forced into concentric, nested rings of scar tissue which do not communicate freely and thus do not contribute to an integral circumferential scar capsule.

It will be appreciated that the height of these nested hexcel structures may be varied. Also the number, diameter or perimeter of the hexcel structures as well as their wall thickness and shapes and characteristics may be varied. It will be further appreciated that a great number of geometric patterns may be utilized for the purposes described above, including square and circular patterns.

It will be appreciated also that the molded textured covering 58 above may be configured to accept a geometric shaped portion of any of the other coverings described herein. A piece of the woven ePTFE stretch weave cover 62, as an example, is sewn or otherwise suitably affixed to the molded covering 58.